

**REMARKS**

**Summary of Office Action**

As an initial matter, Applicants note with appreciation that the Examiner has indicated consideration of the Information Disclosure Statement filed September 29, 2006 by returning a signed and initialed copy of the Form PTO-1449 submitted therein.

Applicants also note with appreciation that the Examiner has withdrawn all of the previously applied art-based rejections.

Claims 105-112, 119-123, 125-132, 139-141, 147-151, 163, 164, 167, 170, 174-185, 189, 192, 193, 197-199, 206, 207 and 209 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Burrell et al., US 2003/0054046 (hereafter "BURRELL").

Claims 113-118, 124, 133-136, 142-146, 152-162, 165, 166, 168, 169, 171-173, 186, 187, 190, 194, 195, 200-205, 208 and 210 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BURRELL and further in view of Kirkwood et al., US 2004/0241214 (hereafter "KIRKWOOD").

Claims 137, 138 and 196 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BURRELL in view of KIRKWOOD and further in view of U.S. Patent No. 6,903,243 to Burton (hereafter "BURTON").

Claims 105-187, 189, 190 and 192-210 are provisionally rejected under the non-statutory doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-20 and claims 1-34 of co-pending Application Nos. 11/255,956 and 11/255,957.

**Response to Office Action**

Withdrawal of the rejections of record is respectfully requested, in view of the following remarks.

***Response to New Rejection of Claims under 35 U.S.C. § 103(a) over BURRELL***

Claims 105-112, 119-123, 125-132, 139-141, 147-151, 163, 164, 167, 170, 174-185, 189, 192, 193, 197-199, 206, 207 and 209 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over a newly cited document, BURRELL. The rejection essentially alleges that BURRELL discloses or renders obvious all of the elements recited in the rejected claims, making reference in this respect to the abstract and paragraphs [0106], [0108], [0110], [0111], [0120], [0132] and [0197] of BURRELL. Regarding two of the elements recited in all of the present independent claims, i.e., the presence of an antimicrobial metal (silver) in elemental form as such on an (interior) surface of the composite which does not come into direct contact with the skin (wound) and the substantial absence of an antimicrobial metal (silver) in elemental form on exterior surfaces of the composite, the rejection alleges, presumably with reference to Example 1 of BURRELL and particularly paragraph [0197] thereof: "While the applied reference does not teach coating both the interior and exterior sides of the outer dressing layers with silver it would have been obvious to one of ordinary skill in the art to have coated the interior facing sides of the outer dressing layers as well as the exterior facing sides with antimicrobial silver. The skilled artisan would have been motivated by the desire to impart more antimicrobial properties to the article and the fact that the middle absorbent layer is

P24008.A14

designed to hold sufficient moisture next to the skin in order to activate the antimicrobial metal coating, that is to cause release of ions, molecules, atoms or clusters of the antimicrobial metal in order to cause an antimicrobial and anti-inflammatory effect. The most efficient way for this to occur is for the antimicrobial metal layers to be located on the interior of the outer dressing layers. ... Examiner has interpreted the limitation of "exterior surfaces of the composite" to mean the surface that is exposed to visual inspection. In this case the blue indicator layer is located on the exterior surfaces of the composite." Paragraph bridging pages 4 and 5 of the present Office Action.

Applicants respectfully traverse this rejection. Specifically, it is pointed out that all of the independent claims of record (i.e., claims 105, 163, 180, 207 and 208) recite that in the claimed composite substantially no antimicrobial metal (silver metal) is present on exterior surfaces of the composite. BURRELL not only fails to teach or suggest a corresponding composite, but even teaches away therefrom. For example, in paragraph [0114] thereof BURRELL states (emphasis added):

**[0114]** The coated substrate, for example a dressing, preferably includes a nanocrystalline coating of one or more of the antimicrobial metals. The coating is applied to one or more of the dressing layers, but is most preferably applied at least to the skin facing layer.

In other words, according to BURRELL, it is most preferred for the antimicrobial metal to be present on the skin facing layer which means that antimicrobial metal is necessarily present on an exterior surface of the dressing (the skin facing layer), contrary to what is recited in the present independent claims.

With respect to Example 1 of BURRELL, it is not completely clear to Applicants what the Examiner wanted to express with the comments recited above regarding the blue indicator layer being located on the exterior surfaces of the composite. It appears that the Examiner is of the opinion that because the blue indicator layer may be located on exterior surfaces of the composite of Example 1 of BURRELL, the exterior surfaces are free of antimicrobial metal. However, this is clearly not the case. In particular, paragraphs [0192], [0193] and [0197] of BURRELL state (emphases added):

**[0192]** This example shows the preparation of a bilayer nanocrystalline silver coating on a dressing material. A high density polyethylene dressing, DELNET™ or CONFORMANT 2™ was coated with a silver base layer and a silver/oxide top layer to generate a coloured antimicrobial coating having indicator value. The coating layers were formed by magnetron sputtering under the conditions set out in Table 1.

**[0193]** The resulting coating was blue in appearance. A fingertip touch was sufficient to cause a colour change to yellow. The base layer was about 900 nm thick, while the top layer was 100 nm thick.

**[0197]** To form a three layer dressing, two layers of this coated dressing material were placed above and below an absorbent core material formed from needle punched rayon/polyester (SONTARA.TM. 8411). With the silver coating on both the first and third layers, the dressing may be used with either the blue coating side or the silver side in the skin facing position. For indicator value, it might be preferable to have the blue coating visible. The three layers were laminated together by ultrasonic welding to produce welds between all three layers spaced at about 2.5 cm intervals across the dressing. This allowed the dressing to be cut down to about 2.5 cm size portions for smaller dressing needs while still providing at least one weld in the dressing portion.

Further, regarding the preparation of the blue indicator layer, BURRELL provides the following information in paragraphs [0115] to [0117] thereof (emphases added):

**[0115]** The nanocrystalline coating is most preferably formed with atomic disorder in accordance with the procedures set out above and as described in WO 93/23092, WO 95/13704, and WO98/41095, and as set out below. Most preferably, the coating is formed as a multilayer coating of the antimicrobial metals, having a top and a base layer, as set below, to produce an interference colour. In this way, the coating

provides not only the active ingredient for the treatment of inflammatory skin conditions, but also acts as an indicator of activation of the dressing. As the top layer of the coating is activated with an alcohol or water-based electrolyte, such as sterile water or ethanol, even minor dissolution of the antimicrobial metal results in a detectable colour change, indicating that the coating has been activated. If there is no colour change, additional moisture might be provided to the dressing by adding water, until a colour change is detected. Once activated, the dressing should be maintained in a moist condition, for example by the addition of sterile water, if necessary.

**[0116]** iii) Multilayer Nanocrystalline Coatings of Antimicrobial Metals With Interference Colour

**[0117]** The coated substrates, for example dressings may include the antimicrobial metal coating formed with at least two metal layers, a base layer and a top layer over the base layer, so as to produce an interference colour, as set forth in WO 98/41095, the teachings of which are incorporated herewith by reference. The indicator colour can function as an indicator when contacted with a water or alcohol based electrolyte, since the coating will change colour. An exemplary multilayer nanocrystalline coating of silver with a blue interference colour is set forth in Example 1.

Regarding the bi-layer interference coating BURRELL refers to another document, i.e., WO 98/41095. This document claims priority from U.S. patent application No. 08/818,869, which matured into U.S. Patent No. 6,333,093 to Burell et al. The '093 patent, which has been cited in previous Office Actions, discusses the interference coating as follows (col. 2, line 66 to col. 3, line 24, emphases added):

The base layer might be provided as a substrate (ex. medical device) which is partly reflective such that it can provide an interference colour when covered with a partly reflective, partly transmissive top layer. Preferably the base layer is formed from a metal selected from Ag, Au, Pt, Pd, Cu, Ta or Al, with Au, Ag, Pt, Pd and Cu being most preferred. Preferably both the top and base layers are formed from anti-microbial metals formed with atomic disorder. The top layer is most preferably formed from Au or Ag.

Most preferably, the top layer is a composite material formed by depositing the anti-microbial metal in a matrix with atoms or molecules of a different material, wherein the different material provides atomic disorder in the matrix. The different material may be a biocompatible metal such as Ta, Ti, Nb, V, Hf, Zn, Mo, Si or Al, or oxides, nitrides, carbides, borides, halides, sulphides or hydrides of such biocompatible metals. Alternatively, the different material may be atoms or molecules absorbed or trapped from the atmosphere used in a vapour deposition process,

P24008.A14

including oxygen, nitrogen, hydrogen, boron, sulphur or halogens. As a further alternative, the different material may be an oxide, nitride, carbide, boride, halide, sulphide or hydride of an anti-microbial metal. Most preferably, the top layer is formed with Ag as the matrix metal, and either or both or silver oxide and absorbed or trapped oxygen as the different material.

It should be readily apparent from the above-recited statements from the '093 patent that while the top layer of the interference coating of the composite of Example 1 of BURRELL may be a silver/oxide layer, the corresponding composite still has elemental silver on exterior surfaces thereof. In other words, the top layer is not a layer of silver oxide, but a layer of silver/oxide, meaning that it consists of a matrix of elemental silver which contains inclusions of silver oxide. In view thereof, a corresponding composite is still in accordance with the most preferred embodiment of BURRELL, i.e., it comprises a coating of an antimicrobial metal on the skin facing layer thereof.

For at least all of the foregoing reasons, BURRELL neither teaches nor suggests the subject matter of any of the independent claims of record (and the claims dependent therefrom). In view thereof, Applicants refrain from commenting on the further allegations with respect to BURRELL set forth in the present Office Action. Applicants' silence in this regard must, however, not be construed as admission that any of these allegations is meritorious.

Applicants submit that in view of the foregoing the rejection of claims 105-112, 119-123, 125-132, 139-141, 147-151, 163, 164, 167, 170, 174-185, 189, 192, 193, 197-199, 206, 207 and 209 under 35 U.S.C. § 103(a) over BURRELL is unwarranted and should be withdrawn, which action is respectfully requested.

***Response to Rejection of Claims over BURRELL/KIRKWOOD/BURTON***

Dependent claims 113-118, 124, 133-136, 142-146, 152-162, 165, 166, 168, 169, 171-173, 186, 187, 190, 194, 195, 200-205 and 210 and independent claim 208 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BURRELL and further in view of KIRKWOOD. Dependent claims 137, 138 and 196 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BURRELL in view of KIRKWOOD and further in view of BURTON.

Applicants respectfully traverse these rejections as well and request withdrawal thereof, but refrain from commenting on the corresponding allegations set forth in the present Office Action (without admitting that any of these allegations is meritorious) because with one exception, the rejections relate to dependent claims and it has already been set forth above why the claims from which the rejected claims depend are not rendered obvious by BURRELL.

Regarding the rejection of independent claim 208 it is pointed out that this claim, like all of the other independent claims of record, recites that substantially no silver metal is present on exterior surfaces of the composite, wherefore claim 208 is not rendered obvious for at least all of the reasons which have been set forth above with respect to the rejection under 35 U.S.C. § 103(a) over BURRELL alone.

Further, Applicants submit that there is no motivation to combine the teachings of BURRELL and KIRKWOOD because the teachings of these two documents differ in critical aspects thereof. For example, BURRELL is directed to coatings of silver metal whereas KIRKWOOD merely suggests (i.e., does not even exemplify) a coating of microparticles or

P24008.A14

microspheres loaded with colloidal silver.

Also, while according to paragraph [0114] of BURRELL the silver coating is most preferably present on at least the skin facing layer of a dressing, KIRKWOOD teaches that the loaded microparticles or microspheres are located on a side of the skin facing layer which is opposite to the side which faces the skin. It is not seen how under these circumstances one of ordinary skill in the art would be motivated to combine the teachings of BURRELL and KIRKWOOD.

***Response to Provisional Obviousness-Type Double Patenting Rejections***

Applicants again respectfully request that the provisional claim rejections under the doctrine of obviousness-type double patenting over claims 1-20 and claims 1-34 of co-pending Application Nos. 11/255,956 and 11/255,957 be held in abeyance until the Examiner has indicated allowable subject matter in this and the two co-pending applications.

**CONCLUSION**

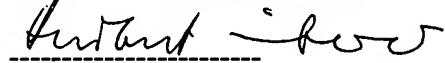
In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.



P24008.A12

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